

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM A. HASELTINE
and
ERNEST TERWILLIGER

Appeal No. 95-2208
Application 07/987,572¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

¹ Application for patent filed December 8, 1992. According to appellants, this application is a continuation of Application 07/249,918, filed September 27, 1988, now abandoned.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 11. Subsequent to the final rejection, appellants canceled claims 3, 4, and 7 and added claims 15 through 17. Thus, claims 1, 2, 5, 6, 8 through 11 and 15 through 17 are before us for consideration. Claims 12 through 14 are pending, but have been withdrawn from consideration by the examiner.

Claims 1 and 2 are illustrative of the subject matter on appeal and read as follows:

1. A vector comprising:

(a) a sufficient number of nucleotides corresponding to an HIV genome to express HIV gene products necessary for viral replication and infectivity (the HIV segment); and inserted in the HIV segment (I) in a region of non-essential HIV nucleotide sequences or (ii) instead of a region of non-essential HIV nucleotide sequences

(b) a sufficient number of nucleotides corresponding to a heterologous gene to express a functional protein (the heterologous gene segment).

2. The vector of claim 1, wherein the heterologous gene segment corresponds to a marker gene.

The examiner states at page 4 of the examiner's answer (Paper No. 22, August 15, 1994) that prior art is not relied upon in support of the rejection of the claims on appeal.²

² The examiner lists four documents at page 5 of the examiner's answer, stating that the references are "relied upon for support of the arguments presented here and below." As stated in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970) "[w]here a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection." Since the examiner has stated that he does not rely upon prior art in support of the rejection of record, we have not considered the four references
(continued...)

Claims 1, 2, 5, 6, 8 through 11, and 15 through 17 stand rejected under 35 U.S.C. § 112, first paragraph (enablement). We reverse.

DISCUSSION

The statement of the rejection is set forth on pages 5-7 of the examiner's answer. In essence, the examiner would have appellants limit the claims on appeal to the specific vector described in the working examples of this application. The examiner has set forth four separate reasons why the claims should be so limited.

In considering the four reasons, we find that the examiner has failed to take into account the proper legal standards in determining whether the subject matter of a given claim is enabled as required by 35 U.S.C. § 112, first paragraph. As a consequence, the examiner has not engaged in the fact finding needed in order to properly reach a conclusion of non-enablement under this section of the statute.

As set forth in In re Marzocchi, 439 F.2d 220, 223, 160 USPQ 367, 369 (CCPA 1971), it is the examiner's initial burden to explain why one skilled in the art would doubt the enabling statements set forth in the supporting specification of a patent application. Here, the examiner has focused on the working examples contained in the supporting specification and has not taken into account the broader statements contained in this

²(...continued)
in reaching our decision.

document. Furthermore, it does not appear that the examiner has taken into account the prior art in reaching his conclusion of non-enablement. This is legal error. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ 1001, 1005 (Fed. Cir. 1997)(“A specification need not disclose what is well known in the art.”).

To the extent the examiner has raised the issue of “undue experimentation”, the examiner has only concluded that making and using certain embodiments within the scope of the claims on appeal would require undue experimentation. The examiner has not favored the record with any fact finding in support of this conclusion. As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996)

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation “must not be unduly extensive.” Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413

(Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

Absent a more fact-based explanation of the rejection premised upon the correct legal standards, we do not find that the examiner has carried his initial burden of establishing reasons of unpatentability. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). As a consequence, we reverse the rejection under 35 U.S.C. § 112, first paragraph (enablement).

The decision of the examiner is reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
)	
)	
)	
WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
)	

Appeal No. 95-2208
Application 07/987,572

HUBERT C. LORIN)
Administrative Patent Judge)

Ronald I. Eisenstein
Peabody and Brown
101 Federal Street
Boston, MA 02110